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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,316	12/08/2003	John Favuzzi	P140US01	5097

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DAKO, GLOBAL INTELLECTUAL PROPERTY
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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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09/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,316	Applicant(s) FAVUZZI ET AL.	
	Examiner P. Kathryn Wright	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-98 is/are pending in the application.
- 4a) Of the above claim(s) 49-68, 84, 85 and 91-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-83 and 86-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 69-83, and 86-90 in the reply filed on September 04, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "sample immerser" and the "fluid recycle element" (claim 80) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "sample immerser element" and "fluid recycle element" (claim 80).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 69-83 and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 recites "the sample immerser element comprises a slide rack having the slide and configured to accommodate a plurality of slides". It is not clear how the "sample immerser element" includes a slide rack with a plurality of slides since the sample immerser element is defined in parent claim 86 as "adapted to immerse the at least one tissue sample in at least one fluid". How does the sample immerser element include both the slide rack and the ability to immerse the slides? It is unclear from the claims, as currently presented, what element(s) corresponds to the "sample immerser element". Furthermore, the specification does not clarify what is meant by the "sample immerser element", therefore it is not possible to determine the metes and bounds of the claims as currently written.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 69-75, 78, 81-83 and 86-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Copeland et al. (US Patent no. 5,595,707), (hereinafter "Copeland").

Copeland teaches an automatic strainer system for staining at least one tissue sample. Specifically, Copeland teaches a slide 26 having at least one tissue sample (e.g., 250; Fig. 13) disposed thereon and a plurality of reagent application elements (10 carousel, 12 reagent bottle, 18 actuator, 307 nozzle; see for example col. 6, lines 33+

and Fig. 15) which work in concert to apply the at least one reagent to the at least one tissue sample when the slide is disposed substantially horizontally.

Copeland also teaches a plurality of sample immerser elements. The Office considers the sample immerser element to read on Copeland's heated air supply chamber 28 and manifold 30 and rinse stations (i.e., 200, 202, 204, 220, 222, 224; see Figs. 13 and 17). Note that Copeland teaches two or more "fluid reagents" are added to the sample on the slide (col. 9, lines 16+.) The Office considers the heated air supply chamber, manifold and rinse stations of Copeland "adapted to" immerse the at least one tissue sample in the at least one fluid for application to the at least one tissue sample during at least one pre-treatment operation performed on the at least one tissue sample prior to the staining operation. The at least one fluid is contained within a fluid containment element which includes a heating member (heated rinse supply channel 230), see for example col. 7, lines 44-54 and col. 9, lines 57+.

Please note that the claims limitation "immerse" has been interpreted as coving the sample completely in fluid and does not require slide be "submerged" in fluid. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Only structural language is determinative of the metes and bounds of a patent claim. Functional recitations, standing alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Nevertheless, functional language in the claims must be

given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language. However, an applicant must establish that what is expressly taught by the prior art does not inherently function in the manner required by the claim.

Claims 70-73 and 86 describe the manner in which the staining apparatus is intended to be employed. Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., pre-treatment operation, target retrieval, removal of an embedding medium, etc.) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

With respect to claims 81-83, Copeland teaches a rotating slide rack 24 configured to accommodate a plurality of slides 26 and a drawer assembly 22 "adapted to" retract from the system, wherein the drawer assembly comprises the slide rack on the top surface. Note that the phrase "drawer assemblies" does not include any structural limitations which would serve to distinguish from the plates 22, 40 of Copeland. Giving the claims the broadest reasonable interpretation, the Examiner takes the position that the drawer assemblies of Copeland are "adapted to retract from the system" when disassembled as shown in Fig. 2. In addition, the drawer assemblies "cooperates with" the fluid containment elements 12, hot supply tank 44, transfer tank 50, and waste tank 58 in that the drawers support these elements when mounted on top of their respective drawer assemblies (see Fig. 2). USPTO personnel are to give claims

their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997).

Limitations appearing in the specification but not recited in the claim should not be read into the claim. Claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily. See *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003)), *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320,1322 (Fed. Cir. 1989). Furthermore, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 88, the phrase "dip tank" does not include any structural limitations which would serve to distinguish from the fluid containment elements 12 of Copeland.

9. Claims 69-73, 75-77, 79-80, and 86-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkie et al. (US Patent no. 4,092,952), (hereinafter "Wilkie").

Wilkie teaches an automatic strainer system for staining at least one tissue sample. Specifically, Wilkie teaches a slide S having said at least one tissue sample disposed thereon and a reagent application element (91, stain container) which apply reagent to the at least one tissue sample when the slide is disposed substantially horizontally (see for example col. 3, lines 60+ and Fig. 2).

Wilkie also teaches a sample immerser element (e.g., slide rack 193) for immersing a plurality of slides having the at least one tissue sample in at least one fluid for application to the at least one tissue sample during at least one pre-treatment operation performed on the at least one tissue sample prior to the staining operation. The sample immerser element also includes a slide immerser and slide positioner element 207, 215, 225 "adapted to" lower the slide into the fluid containment elements containing fluid (e.g., 43, 79) and rotate the slide to a substantially vertical disposition (see, for example, col. 5, lines 49+ and Figs. 2-4). Note that slide-drying chamber 43 (one fluid containment element) includes a heating element 45 (electric resistance heater).

Please note the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claims 70-73 and 86 describe the manner in which the staining apparatus is intended to be employed. Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., pre-treatment operation, target retrieval, removal of an embedding medium, etc.) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

With respect to claims 79-80, Wilkie teaches a pneumatic element (pump 59) adapted to transfer liquid from a supply tank 51 to a transfer tank (filter tank 101) to the

fluid containment element (rinse tank 79; Fig. 4) and to a drain element (87; Fig. 5) which removes the liquid from the fluid containment element to the transfer tank and the waste collection tank at outlet 109.

Furthermore, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 88, the phrase "dip tank" does not include any structural limitations which would serve to distinguish from the fluid containment elements (e.g., 43, 79) of Wilkie.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 24, 2007

pkw


Jill Warden
Supervisory Patent Examiner
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Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/2007;10/2006;8/2005;4/2004;12/2003.